

<div>Frederick National Laboratory for Cancer Research</div> <div>sponsored by the National Cancer Institute</div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 1 of 21

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Approver Name	Title	Signature/Date

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Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 2 of 21

1. PURPOSE

- 1.1. The purpose of this procedure is to describe the general use and maintenance of the Luminex FLEXMAP 3D instrument.

2. SCOPE

- 2.1. This procedure applies to the HPV Serology Laboratory located at the Advanced Technology Research Facility, Room C2007.

3. REFERENCES

- 3.1. HSL_EQ_028.01: Use and Weekly Maintenance of the FLEXMAP 3D
- 3.2. HSL_EQ_028.02: FLEXMAP 3D Performance Maintenance Form
- 3.3. HSL_GL_001: Waste Disposal at the Advanced Technology Research Facility
- 3.4. HSL_GL_002: Equipment Qualification and Calibration in the HPV Serology Laboratory
- 3.5. HSL_GL_003: Good Documentation Practices for the HPV Serology Laboratory
- 3.6. HSL_GL_006: Reagent Preparation for the HPV Serology Laboratory
- 3.7. HSL_GL_007: Reagent and Chemical Expiry in the HPV Serology Laboratory
- 3.8. HSL_GL_008: Laboratory Flow and Gowning Procedures for the HPV Serology Laboratory
- 3.9. HSL_GL_009: HPV Serology Laboratory BSL-2 Procedures
- 3.10. HSL_GL_010: Control and Request of Documents in the HPV Serology Laboratory

4. RESPONSIBILITIES

- 4.1. The Research Associate, hereafter referred to as analyst, is responsible for reviewing and following this procedure.
- 4.2. The Scientific Manager or designee is responsible for training personnel in this procedure and reviewing associated documentation.
- 4.3. The Quality Assurance Specialist is responsible for quality oversight and approval of this procedure.

5. REAGENTS, CHEMICALS AND EQUIPMENT

- 5.1. Sodium Hydroxide (Warehouse, Cat # 68100251 or equivalent)

<div>Frederick National Laboratory for Cancer Research</div> <div>sponsored by the National Cancer Institute</div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 3 of 21

- 5.2. Barcode Scanner (Luminex, Cat # CN-PC03-01)
- 5.3. Air Filter: Access Door (Luminex, Cat # CN-0222-01)
- 5.4. Air Filter: XY Platform (Luminex, Cat # CN-0229-01)
- 5.5. Air Filter: HEPA (Luminex, Cat # CN-0001-01)
- 5.6. Syringe Cylinder with seal, 500 uL (Luminex, Cat # CN-0013-01)
- 5.7. Syringe Seal (Quantity 4) (Luminex, Cat # CN-0014-01)
- 5.8. Sheath Filter with quick disconnect (Luminex, Cat # CN-0010-01)
- 5.9. Sample Probe Height Adjustment Kit (Luminex, Cat # CN-0263-01)
- 5.10. Cable, USB (A to B) (Luminex, Cat # CN-0227-01)
- 5.11. Fuse (6 amp) (Luminex, Cat # CN-0226-01)
- 5.12. Sample Probe Needle (Luminex, Cat # CN-0221-01)
- 5.13. Off-plate Block (Luminex Cat # CN-0225-01)
- 5.14. 6 Month PM (Preventive Maintenance) Kit (Luminex, Cat # CN-0215-01)
- 5.15. Probe Height Adjustment Plate (Luminex, Cat # CN-0298-01)
- 5.16. Heater Block for 96-Well Microtiter Plates (Luminex, Cat # CN-0224-01)
- 5.17. Heater Block for 384-Well Microtiter Plates (Luminex, Cat # CN-0223-01)
- 5.18. xMAP® Sheath Fluid, 20 L (Luminex, Cat # 40-50000)
- 5.19. xMAP Sheath Fluid Concentrate (20x), 1 L (Luminex Cat # 40-75680)
- 5.20. FLEXMAP 3D® Calibration Kit (Luminex, Cat # F3DIVD-CAL-K25)
- 5.21. FLEXMAP 3D Performance Verification Kit (Luminex, Cat # F3DIVD-PVER-K25)
- 5.22. Clorox Bleach, Concentrated (Warehouse, Cat # 68100251 or equivalent)
- 5.23. Ster-ahol (VWR, Cat # 14003-358 or equivalent)
- 5.24. Type II water

<div>Frederick National Laboratory for Cancer Research</div> <div>sponsored by the National Cancer Institute</div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 4 of 21

6. HEALTH AND SAFETY CONSIDERATIONS

- 6.1. Proper safety precautions should be taken while working in a laboratory setting. This includes, but is not limited to, proper protective equipment such as lab coats, safety glasses, closed-toe shoes, and non-latex gloves.
- 6.2. Refer to the respective SDS when working with any chemicals.
- 6.3. Refer to “HSL_GL_001: Waste Disposal at the Advanced Technology Research Facility” regarding waste disposal processes at the ATRF.
- 6.4. See “Attachment 1: Safety Considerations” for specific instrument regulatory and safety information.

7. DEFINITIONS

Term	Definition
FME	Facilities, Maintenance and Engineering
HPV	Human Papillomavirus
HSL	HPV Serology Laboratory
NaOH	Sodium hydroxide
PM	Performance Maintenance
SDS	Safety Data Sheets
SOP	Standard Operating Procedure
Type II water	Pure/Analytical Grade, used for standard applications
xPonent	Software used with the Luminex FLEXMAP 3D Instrument

8. DAILY USE AND MAINTENANCE

Note: Daily maintenance must only be performed when instrument is in use. Complete “HSL_EQ_028.01: Use and Weekly Maintenance of the FLEXMAP 3D” when performing Daily Use and Maintenance.

- 8.1. Use xPonent to perform the instrument system initialization.
 - 8.1.1.1. There are three options for initialization (1. Warmup, fluidics; 2. Warmup, fluidics, verification; 3. Warmup, fluidics, verification and calibration). Choose the appropriate option for the tasks being performed.
- 8.2. Prior to starting the instrument, confirm all fluid levels are appropriate and waste is not going to overflow. Do not move waste line vertically while instrument is in use.
- 8.3. Run an automatic Shutdown protocol at the end of each day, after instrument has been used and/or maintenance performed.

<div>Frederick National Laboratory for Cancer Research</div> <div>sponsored by the National Cancer Institute</div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 5 of 21

9. WEEKLY MAINTENANCE

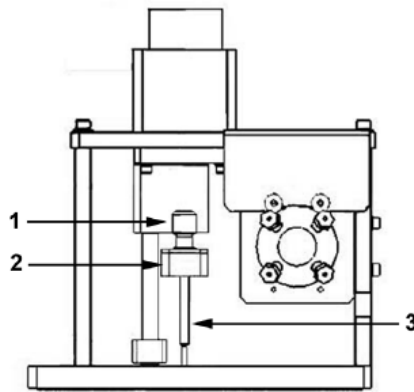
Note: Complete “HSL_EQ_028.01: Use and Weekly Maintenance of the FLEXMAP 3D” when performing Weekly Maintenance.

- 9.1. Use the xPONENT software to perform a weekly maintenance routine.
- 9.2. Perform a clog removal routine using sodium hydroxide (NaOH).
 - 9.2.1. Add 0.1 N NaOH to reservoir RB1 on the off-plate reagent block.
 - 9.2.2. Use the software to perform a clog removal routine.
- 9.3. Clean the sample probe.
 - 9.3.1. Use the software to execute STOP if a plate is running. Refer to the software manual for instructions.
 - 9.3.2. Remove the sample probe.
 - 9.3.3. Open the right front door of the FLEXMAP 3D.
 - 9.3.4. Unscrew the Cheminert® fitting on top of the probe, completely.
 - 9.3.5. Grasp the probe gently and push up.
 - 9.3.6. Lift the probe out of the top of the probe holder.
 - 9.3.7. Clean the sample probe using a bath sonicator or a 10 mL syringe. If you are using a bath sonicator, place the tip of the sample probe in the bath sonicator for 2 to 5 minutes or place the probe in a clean tube containing water which will then be placed in a sonicator. If you are using a syringe, force Type II water through the tip of the sample probe to the large end. This dislodges any debris clogging the tip.
 - 9.3.8. Replace the sample probe and tightly screw in the Cheminert fitting.
 - 9.3.9. Use the software to perform an automatic probe height adjustment.

Note: Perform an automatic probe height adjustment any time the probe is removed.

Note: For information on calibrating the probe correctly, refer to the appropriate Luminex software manual.

<div>Frederick National Laboratory for Cancer Research</div> <div>sponsored by the National Cancer Institute</div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 6 of 21



1	Cheminert® fitting - Unscrew as shown
2	Probe Holder
3	Sample Probe, Push up and out of probe holder as shown

- 9.4. Calibrate the FLEXMAP 3D after the other weekly maintenance has been performed.

10. MONTHLY MAINTENANCE

Note: Complete “HSL_EQ_028.02: FLEXMAP 3D Performance Maintenance(PM) Form” when performing monthly maintenance/PM.

- 10.1. Clean the exterior surfaces monthly.
- 10.1.1. Turn off the FLEXMAP 3D® and unplug the power cord.
 - 10.1.2. Clean all exterior surfaces with a mild detergent, cavicide, or 10% Bleach; Rinse with Type II Water.
 - 10.1.3. Open both doors of the system.
 - 10.1.4. Clean all accessible surfaces with a mild detergent, cavicide, or 10% Bleach; Rinse with Type II Water.
 - 10.1.5. Dry any unpainted metal surfaces to prevent corrosion.
 - 10.1.6. Plug in the power cord and turn on the FLEXMAP 3D.

11. SEMI-ANNUAL MAINTENANCE

Note: Complete “HSL_EQ_028.02: FLEXMAP 3D Performance Maintenance(PM) Form” when performing semi-annual maintenance/PM. Apply a “PM” sticker once maintenance is complete.

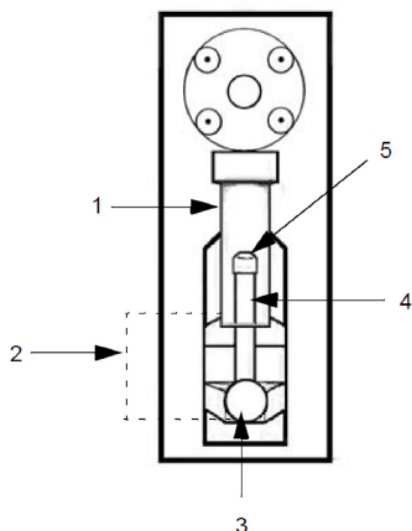
<div>Frederick National Laboratory for Cancer Research</div> <div>sponsored by the National Cancer Institute</div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 7 of 21

11.1. Replacing the Syringe Teflon Seals

- 11.1.1. Turn off the FLEXMAP 3D® and unplug the power cord.
- 11.1.2. Open the right front door of the FLEXMAP 3D.
- 11.1.3. Locate the syringe (glass cylinder with a metal rod plunger).
- 11.1.4. Loosen the set screw on the syringe arm (at the bottom of the syringe) and push the syringe arm down.

Note: The syringe arm is tight. Be prepared to use some force to push it down.
- 11.1.5. Unscrew the syringe from the top of its housing.
- 11.1.6. Pull the plunger out of the syringe.
- 11.1.7. Remove and replace the white plunger seal (at the top of the plunger) and the black O-ring inside the seal.
- 11.1.8. Return the plunger to the syringe.
- 11.1.9. Screw the syringe back into its housing.
- 11.1.10. Return the syringe arm to its original position. The bottom of the plunger fits into the indentation in the syringe arm.
- 11.1.11. Hand-tighten the set screw on the syringe arm.
- 11.1.12. Plug in the power cord and turn on the FLEXMAP 3D.
- 11.1.13. Use the software to run two **Prime** commands, watching for any leaks in the syringe area.
- 11.1.14. Close the right front door.

<div>Frederick National Laboratory for Cancer Research</div> <div>sponsored by the National Cancer Institute</div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 8 of 21



1	Glass Syringe Barrel
2	Syringe Arm (between dotted lines)
3	Set Screw
4	Syringe Plunger
5	Plunger Seal (contains O-ring)

11.2. Replace the HEPA Filter, located behind the panel on the left front side of the fluidics bay.

11.2.1. Turn off the FLEXMAP 3D® and unplug the power cord.

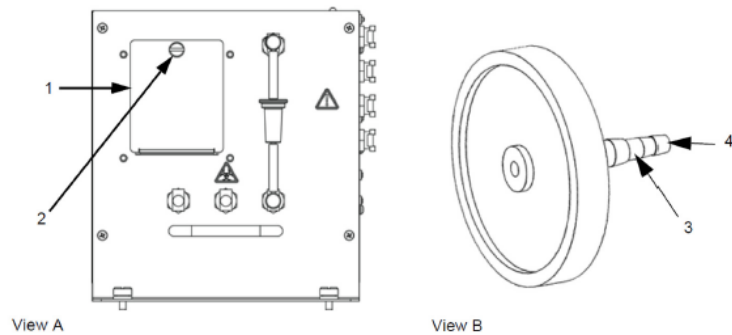
11.2.2. Open the left door and locate the HEPA filter panel on the front of the fluidics bay as shown in *Figure 28, "HEPA Filter"*.

11.2.3. Remove the screw at the top of the panel and open the panel door as shown in *Figure 28, "HEPA Filter"*.

11.2.4. Grasp the tubing and pull the filter 3 to 4 inches from the unit.

11.2.5. Remove the filter with one hand and hold the tubing with the other hand. Do not allow the tubing to fall inside the system.

<div><div><div>Frederick National Laboratory</div><div>for Cancer Research</div><div>sponsored by the National Cancer Institute</div></div></div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 9 of 21



View A	Front of fluidics bay	View B	HEPA Filter
1	Filter panel	3	Filter Stem
2	Screw - Remove as indicated in steps	4	Attachment point for tubing

11.3. Clean the ventilation filters.

Note: Each filter has at least one imprinted arrow on its metal frame. The arrow indicates the direction of the air flow. Install the filters so that the arrows are at the correct locations and point in the correct direction.

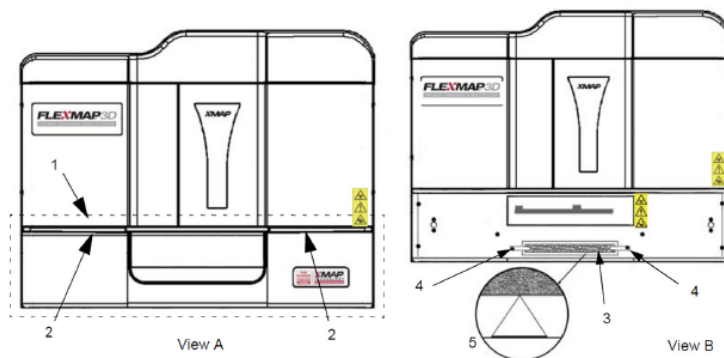
- 11.3.1. Turn off the FLEXMAP 3D and unplug the power cord.
- 11.3.2. Remove the XY cover by gently grasping the ventilation holes and pulling the cover straight out.
- 11.3.3. Slide clamps off the silver filter inside the cover and remove the filter.
- 11.3.4. Open the front doors. Slide clamps off the left and right silver door filters and remove the filters.
- 11.3.5. Clean the filters with a vacuum or with Type II water.
- 11.3.6. Stand the filters upright to air dry. Allow filters to completely dry prior to reinstallation.

Use and Maintenance of the Luminex FLEXMAP 3D

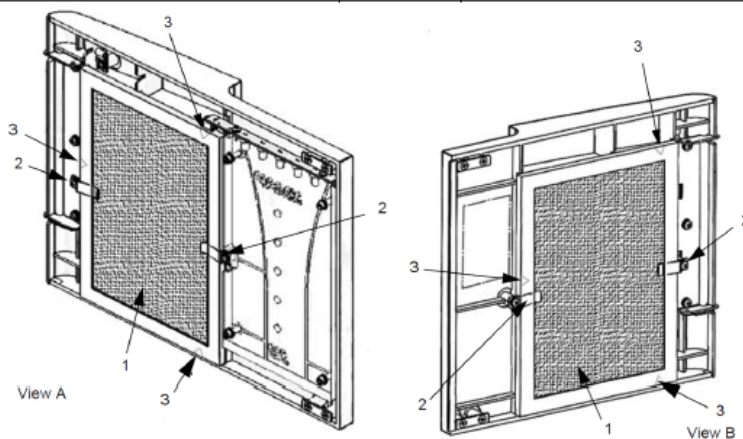
Document ID: HSL_EQ_028

Version 1.0

Page 10 of 21



View A	Front of the FLEXMAP 3D® system with XY cover in place	View B	Front of the FLEXMAP 3D system with XY cover removed
1	XY Cover (inside dotted lines)	4	Filter Clamp
2	Location of ventilation holes on top of XY cover (visible only when doors are open)	5	Incised Arrow
3	Filter		



View A	Right front door, viewed from inside
View B	Left front door, viewed from inside
1	Filter
2	Filter Clamp
3	Incised Arrow

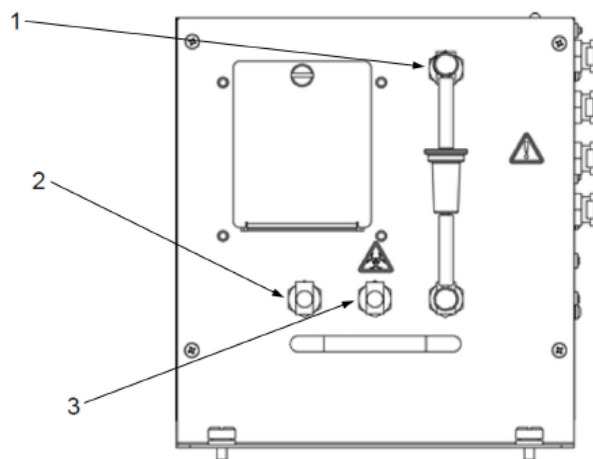
<p>Frederick National Laboratory for Cancer Research</p> <p><i>sponsored by the National Cancer Institute</i></p>	<p>HPV Serology Laboratory Standard Operating Procedure</p>
<p>Use and Maintenance of the Luminex FLEXMAP 3D</p>	
<p>Document ID: HSL_EQ_028</p>	<p>Version 1.0</p> <p>Page 11 of 21</p>

12. ANNUAL MAINTENANCE

Note: Complete “HSL_EQ_028.02: FLEXMAP 3D Performance Maintenance(PM) Form” when performing annual maintenance/PM. Apply a “PM” sticker once maintenance is complete.

12.1. Replace the FLEXMAP 3D® sheath filter:

- 12.1.1. Turn off the FLEXMAP 3D and unplug the power cord.
- 12.1.2. Open the left door on the FLEXMAP 3D and locate the sheath filter on the front of the fluidics bay.
- 12.1.3. Disconnect the filter by pushing down on the metal clamps at each quick-disconnect point.
- 12.1.4. Connect the new sheath filter, matching up the color-coded fittings. The arrow on the sheath filter should be pointing up.
- 12.1.5. Close the left door.
- 12.1.6. Plug in the power cord and turn on the FLEXMAP 3D.
- 12.1.7. Use the software to run two **Prime** commands.



1	Top quick-disconnect point
2	Sheath Filter
3	Bottom quick-disconnect point

<div>Frederick National Laboratory for Cancer Research</div> <div>sponsored by the National Cancer Institute</div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 12 of 21

13. AS NEEDED MAINTENANCE

Note: Complete “HSL_EQ_028.01: Use and Weekly Maintenance of the FLEXMAP 3D” when performing as needed maintenance/PM.

13.1. Replace a fuse on the FLEXMAP 3D as needed.

13.1.1. Turn off the FLEXMAP 3D and unplug the power cord.

13.1.2. Use a small, flat-blade screwdriver to open the module door on the lower left corner of the back of the system. The door opens downward. Inside are two cartridges, a red one on top and a black one on the bottom.

13.1.3. Use the screwdriver to remove the red cartridge.

13.1.4. Check both fuses in the cartridge for damage. A fuse can display physical evidence of damage, for example, broken wire or blackened glass; if the fuse displays no physical evidence of damage, test it for continuity with a voltmeter.

13.1.5. Replace damaged fuses with the type specified on the sticker to the right of the power input module.

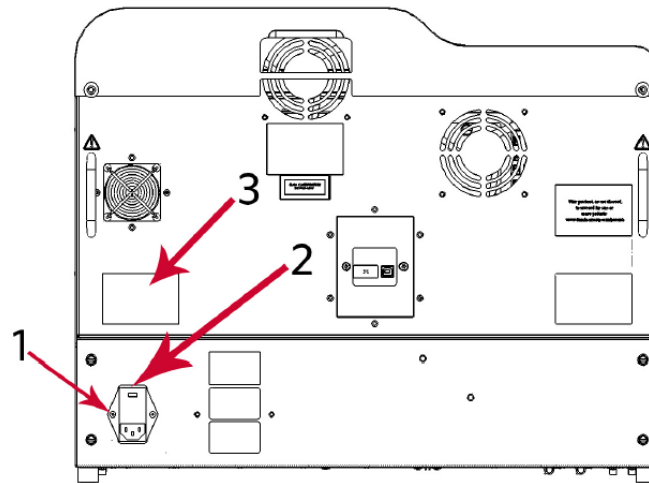
13.1.6. Replace the red cartridge.

13.1.7. Shut the module door.

13.1.8. Plug in the power cord and turn on the FLEXMAP 3D.

Note: If your FLEXMAP 3D is not on a swivel base and requires moving in order for you to access the back of the system, use the software to re-calibrate and re-verify the system after the system is restored to its original location.

<div>Frederick National Laboratory for Cancer Research</div> <div>sponsored by the National Cancer Institute</div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 13 of 21



1	Power Module
2	Location to insert screwdriver to open module door, as referenced above
3	Fuse Information

14. TROUBLESHOOTING

Note: Refer to Users Manual when a specific page is listed in the Troubleshooting section of this procedure.

14.1. Power Supply Problems

Symptom	Possible cause	Solution
The FLEXMAP 3D® will not turn on.	The power cord is disconnected.	Plug in the power cord.
	No voltage is coming from the electrical outlet.	Verify that the electrical outlet is operational.
	The power supply is faulty.	Contact Luminex "Technical Support" on page 48.
	A fuse is burned out.	See "Troubleshooting" on page 41. Use extreme care when replacing a fuse.
Fuses continue to open (blow).	A component has a short circuit.	Contact Luminex "Technical Support" on page 48.

<div>Frederick National Laboratory for Cancer Research</div> <div>sponsored by the National Cancer Institute</div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 14 of 21

14.2. Communication Problems

Symptom	Possible cause	Solution
The PC cannot establish communication with the FLEXMAP 3D.	The communication cable is unplugged or plugged into the wrong port.	Plug in or move the communications cable.
	The FLEXMAP 3D is not turned on.	Turn off the PC. Turn on the FLEXMAP 3D and then turn on the PC.

14.3. Pressurization Problems

Symptom	Possible cause	Solution
Pressurization fails or pressure is too low.	The sheath and waste lines are not fully connected.	Check the lines between the sheath and waste bottles and the FLEXMAP 3D®.
	The sheath or waste fittings are cracked.	Inspect the fittings to be sure they form a tight seal. If not, contact Luminex® <i>“Technical Support” on page 48.</i>
	The system has a leak.	Check for leaks. A leak is obvious if there is fluid on the surface where the FLEXMAP 3D sits. See <i>“Fluid Leaks” on page 42.</i>
	The compressor does not engage.	Use the software to run a Prime command. If you do not hear the compressor turn on, contact Luminex <i>“Technical Support” on page 48.</i>

14.4. Fluid Leaks

Symptom	Possible cause	Solution
Fluid is pooled around the FLEXMAP 3D®.	Fittings or fluid lines are damaged.	Turn off the system and unplug the power cord to avoid electrical shock. Contact Luminex® <i>“Technical Support” on page 48.</i>
Fluid drips from the sample probe.	The sample probe is clogged.	See <i>“Clogs” on page 42.</i>
	The sample path is clogged.	See <i>“Removing Clogs” on page 31.</i>
	The internal component is faulty.	Contact Luminex <i>“Technical Support” on page 48.</i>

<div>Frederick National Laboratory for Cancer Research</div> <div>sponsored by the National Cancer Institute</div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 15 of 21

Symptom	Possible cause	Solution
Fluid leaks from the front of the instrument.	The syringe seal leaks.	Replace the syringe seal. See <i>"Replacing the Syringe Teflon Seals"</i> on page 33.
	The syringe valve leaks.	Hand-tighten the syringe connection (silver knob) on the syringe valve. Use the software to run a Prime command. If leaks continue, contact Luminex <i>"Technical Support"</i> on page 48. If tightening the connection does not resolve the issue, see <i>"Removing Clogs"</i> on page 31.

14.5. Sample Probe Problems

Symptom	Possible cause	Solution
The sample probe leaks.	The sample probe is clogged.	See <i>"Clogs"</i> on page 42.
The sample arm is stuck in the up or down position.	Internal component is faulty.	Contact Luminex® <i>"Technical Support"</i> on page 48.
	Probe calibration is not done.	Perform the automatic sample probe height adjustment using the software.
The sample arm does not go down smoothly.	The microtiter plate is incorrectly seated.	Adjust the microtiter plate.
	The microtiter plate is warped.	Inspect the microtiter plate. Replace the plate if it is warped.
	The sample probe is bent.	Remove the sample probe from the system roll on a flat surface. If a sample probe is bent and rolled straight more than once, discard the sample probe and replace with a new one. Perform the automatic sample probe height adjustment using the software.

<div>Frederick National Laboratory for Cancer Research</div> <div>sponsored by the National Cancer Institute</div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 16 of 21

14.6. Calibration Problems

Symptom	Possible cause	Solution
Calibration is slow or fails.	The calibration microspheres are not fully suspended.	Vortex the calibration vials to resuspend the microspheres.
	The wrong lot number or target values are entered in the appropriate software user interface.	Check the lot number and target values to make sure they are correct.
	The instrument calibrators are in the wrong well.	Verify that calibration microspheres are in the correct well.
	There are not enough calibrator microspheres in the well.	Add at least five drops of calibrator microspheres to the well. For accurate drop volume, hold the vial upside down at a 90 degree angle to the microtiter plate while dispensing them.
	The calibrator lot is expired.	Use an unexpired bottle of calibrator microspheres.
	The sample probe height is incorrect.	Perform the automatic sample probe height adjustment using the software.
	The sample probe is clogged.	See <i>"Clogs"</i> on page 42.
	There is a partial clog in the instrument.	See <i>"Clogs"</i> on page 42.
	There is air in the instrument. The waste line was moved during instrument operation, resulting in an unstable flow rate.	Perform the automatic sample probe height adjustment using the software. Use the software to run three Prime commands, two Alcohol Flush commands, then three Wash commands with deionized water.
	The waste line was moved during instrument operation, resulting in an unstable flow rate.	Stabilize the waste line during instrument operation. See <i>"Maintaining Fluids"</i> on page 31.
No events are collected during calibration.	There is a problem with fluid levels.	Check the sheath and waste fluid levels. Verify that tubing for both bottles is tightly connected to the instrument. Check that the waste fluid container cap is vented.
	The sample probe is clogged.	See <i>"Clogs"</i> on page 42.
	The Cheminert® fitting is loose.	Tighten the Cheminert fitting.

<div>Frederick National Laboratory for Cancer Research</div> <div>sponsored by the National Cancer Institute</div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 17 of 21

14.7. Verification Problems

Symptom	Possible cause	Solution
The instrument fails verification.	The verification microspheres are not fully suspended.	Vortex the verification vials to resuspend the microspheres.
	The wrong lot number or target values are entered in the appropriate software user interface.	Check the lot number and target values to make sure they are correct.
	The instrument verification microspheres are in the wrong well.	Verify that verification microspheres are in the correct well.
	There are not enough verification microspheres in the well.	Add at least five drops of verification microspheres to the well. For accurate drop volume, hold the vial upside down at a 90 degree angle to the microtiter plate while dispensing them.
	The verification lot is expired.	Use an unexpired bottle of verification microspheres.
	The verification microspheres have been diluted.	Do not dilute the verification microspheres.
	The sample probe height is incorrect.	Perform the automatic sample probe height adjustment using the software.
	The sample probe is clogged.	See "Clogs" on page 42.
	There is air in the instrument.	Verify the sample probe height. Use the software to run three Prime commands, two Alcohol Flush commands, then three Wash commands with deionized water.
	The waste line was moved during instrument operation, resulting in an unstable flow rate.	Stabilize the waste line during instrument operation. See "Maintaining Fluids" on page 31.
	There is a problem internal to the instrument.	Review the log of calibration reports. Check for dramatic changes in temperature, sheath pressure, or voltage. If any of these are present, contact Luminex "Technical Support" on page 48.

15. ATTACHMENTS

15.1. Attachment 1: Safety Considerations

<div>Frederick National Laboratory for Cancer Research</div> <div>sponsored by the National Cancer Institute</div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_EQ_028	Version 1.0	Page 18 of 21

Attachment 1: Safety Considerations

Regulatory Labels and Warnings

The following label appears on the back of the FLEXMAP 3D.

FIGURE 1. Laser Warning Label

CLASS I LASER PRODUCT
IEC 60825-1:2007
Complies with 21 CFR 1040.10
and 1040.11 except for
deviations pursuant to Laser
Notice No. 50,
dated June 24, 2007.
Do not remove cover.
No user-serviceable parts inside


The following label appears above the laser apertures located inside the optics enclosure inside the FLEXMAP 3D.

FIGURE 2. Avoid Exposure Label

AVOID EXPOSURE
**Laser radiation is emitted
from this aperture.**

The following fuse caution label appears on the back of the FLEXMAP 3D®.

FIGURE 3. Fuse Caution Label

 **CAUTION:**
Double Pole/Neutral Fusing
Disconnect power before changing fuse

ATTENTION:
Double pole/fusible sur le neutre
Couper le courant avant de remplacer le fusible


 F6A, 250V

FIGURE 4. Serial Number and Voltage Label

Luminex®

Model FlexMAP 3D

SN: FM3DD08234001

Luminex Corporation
12212 Technology Blvd
Austin, Texas 78727

Manufactured in USA
June 2008

**100-120V~ 6.0A and
200-240V~ 3.0A 47-63 Hz**

<div>Frederick National Laboratory for Cancer Research</div> <div>sponsored by the National Cancer Institute</div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 19 of 21

Safety Practices

Read the following safety information before using the FLEXMAP 3D®. In any situation that you encounter this symbol, consult this manual or other Luminex documentation to determine the nature of the potential hazard and any necessary actions you must take.



CAUTION: The protection provided by the equipment can be impaired or the warranty voided if the FLEXMAP 3D is used in a manner not specified by the instructions or by Luminex Corporation.

General



CAUTION: Keep access doors closed during normal operation. Always observe standard laboratory safety practices.

Electromagnetic Compatibility

The FLEXMAP 3D® complies with the emission and immunity requirements described in IEC/EN 61326-1 and IEC/EN 61326-2-6. Evaluate the electromagnetic environment prior to operation.



WARNING: Do not use the FLEXMAP 3D in close proximity to sources of strong electromagnetic radiation, for example, unshielded intentional RF sources, as these can interfere with proper operation.



WARNING: Always handle the FLEXMAP 3D according to Luminex instructions to avoid any possible interference from its electromagnetic fields.

Lasers

The FLEXMAP 3D® is classified under FDA 21 CFR 1040.10 and 1040.11 as a Class I laser product consisting of two Class IIIb lasers within the instrument. The optional accessory barcode reader is classified as Class II. In accordance with IEC 60825-1, the instrument is classified as Class 1, containing two Class 3b lasers, and including an optional accessory Class 2 barcode reader. The FLEXMAP 3D complies with IEC 60825-1 and 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

All Class 3b laser apertures are located within the FLEXMAP 3D and are contained within a protective housing, accessible only to trained field service technicians. When performing routine maintenance, turn power to the system off and unplug the power cord.



DANGER: Do not, under any circumstances, remove the FLEXMAP 3D instrument cover. Use of controls or adjustments or performance of procedures other than those specified in this manual can result in hazardous radiation exposure.

The barcode reader laser presents a potential hazard to eyesight.



DANGER: Do not stare into the barcode reader beam or shine it into other people's eyes.

<p>Frederick National Laboratory for Cancer Research</p> <p><i>sponsored by the National Cancer Institute</i></p>	<p>HPV Serology Laboratory Standard Operating Procedure</p>
<p>Use and Maintenance of the Luminex FLEXMAP 3D</p>	
<p>Document ID: HSL_EQ_028</p>	<p>Version 1.0</p> <p>Page 20 of 21</p>

Fluids

The FLEXMAP 3D[®] contains fluids. In the event of a fluid leak, turn off all power to the system and disconnect all power cords. The on/off switch is not a method of disconnection; the power cord must be removed from the outlet. Contact Luminex[®] "Technical Support" on page 48 for further information.



DANGER: Do not operate the FLEXMAP 3D in the presence of leaking fluid.

Biohazard

Human and animal samples can contain biohazardous infectious agents.



CAUTION: Where exposure to potentially biohazardous material exists, follow appropriate biosafety procedures and use Personal Protective Equipment (PPE). PPE includes gloves, gowns, laboratory coats, face shields or mask and eye protection, respirators, and ventilation devices. Observe all local, state, federal, and country specific biohazard handling regulations when disposing of biohazardous waste material.

Mechanical Components



WARNING: The FLEXMAP 3D[®] has parts that move during operation.



WARNING: Risk of personal injury is present. The moving parts present puncture, pinching, and hand-crushing hazards. Keep your hands and fingers away from the XY slot, syringe pumps, and sample probe during operation.



CAUTION: Observe all warnings and cautions. Keep the access doors closed during normal operations.

NOTE: If the batch spans more than one plate, the tray ejects automatically when all defined wells have been acquired. A dialog box displays prompting you to insert the next plate.

<div>Frederick National Laboratory for Cancer Research</div> <div>sponsored by the National Cancer Institute</div>	HPV Serology Laboratory Standard Operating Procedure	
Use and Maintenance of the Luminex FLEXMAP 3D		
Document ID: HSL_ EQ_028	Version 1.0	Page 21 of 21

16. REVISION HISTORY

Revision Start Date	Version #	Changes	Reasons
30Jun17	New	Create new SOP describing the general use and maintenance required for the Luminex FLEXMAP 3D.	New SOP.

Frederick National Laboratory for Cancer Research <small>sponsored by the National Cancer Institute</small>		HPV Serology Laboratory Standard Operating Procedure	
Use and Weekly Maintenance of the FLEXMAP 3D			
Form ID: HSL_EQ_028.01 Document ID: HSL_EQ_028		Version 1.0	Page 1 of 1

Equipment ID:

Date	Analyst Initials	Activity	Intended Use
		<input type="checkbox"/> Fluidics <input type="checkbox"/> Verification <input type="checkbox"/> Calibration <input type="checkbox"/> Perform clog removal <input type="checkbox"/> Clean probe <input type="checkbox"/> N/A <input type="checkbox"/> Other:	<input type="checkbox"/> N/A
		<input type="checkbox"/> Fluidics <input type="checkbox"/> Verification <input type="checkbox"/> Calibration <input type="checkbox"/> Perform clog removal <input type="checkbox"/> Clean probe <input type="checkbox"/> N/A <input type="checkbox"/> Other:	<input type="checkbox"/> N/A
		<input type="checkbox"/> Fluidics <input type="checkbox"/> Verification <input type="checkbox"/> Calibration <input type="checkbox"/> Perform clog removal <input type="checkbox"/> Clean probe <input type="checkbox"/> N/A <input type="checkbox"/> Other:	<input type="checkbox"/> N/A
		<input type="checkbox"/> Fluidics <input type="checkbox"/> Verification <input type="checkbox"/> Calibration <input type="checkbox"/> Perform clog removal <input type="checkbox"/> Clean probe <input type="checkbox"/> N/A <input type="checkbox"/> Other:	<input type="checkbox"/> N/A
		<input type="checkbox"/> Fluidics <input type="checkbox"/> Verification <input type="checkbox"/> Calibration <input type="checkbox"/> Perform clog removal <input type="checkbox"/> Clean probe <input type="checkbox"/> N/A <input type="checkbox"/> Other:	<input type="checkbox"/> N/A
		<input type="checkbox"/> Fluidics <input type="checkbox"/> Verification <input type="checkbox"/> Calibration <input type="checkbox"/> Perform clog removal <input type="checkbox"/> Clean probe <input type="checkbox"/> N/A <input type="checkbox"/> Other:	<input type="checkbox"/> N/A
		<input type="checkbox"/> Fluidics <input type="checkbox"/> Verification <input type="checkbox"/> Calibration <input type="checkbox"/> Perform clog removal <input type="checkbox"/> Clean probe <input type="checkbox"/> N/A <input type="checkbox"/> Other:	<input type="checkbox"/> N/A
		<input type="checkbox"/> Fluidics <input type="checkbox"/> Verification <input type="checkbox"/> Calibration <input type="checkbox"/> Perform clog removal <input type="checkbox"/> Clean probe <input type="checkbox"/> N/A <input type="checkbox"/> Other:	<input type="checkbox"/> N/A
		<input type="checkbox"/> Fluidics <input type="checkbox"/> Verification <input type="checkbox"/> Calibration <input type="checkbox"/> Perform clog removal <input type="checkbox"/> Clean probe <input type="checkbox"/> N/A <input type="checkbox"/> Other:	<input type="checkbox"/> N/A
		<input type="checkbox"/> Fluidics <input type="checkbox"/> Verification <input type="checkbox"/> Calibration <input type="checkbox"/> Perform clog removal <input type="checkbox"/> Clean probe <input type="checkbox"/> N/A <input type="checkbox"/> Other:	<input type="checkbox"/> N/A
		<input type="checkbox"/> Fluidics <input type="checkbox"/> Verification <input type="checkbox"/> Calibration <input type="checkbox"/> Perform clog removal <input type="checkbox"/> Clean probe <input type="checkbox"/> N/A <input type="checkbox"/> Other:	<input type="checkbox"/> N/A
		<input type="checkbox"/> Fluidics <input type="checkbox"/> Verification <input type="checkbox"/> Calibration <input type="checkbox"/> Perform clog removal <input type="checkbox"/> Clean probe <input type="checkbox"/> N/A <input type="checkbox"/> Other:	<input type="checkbox"/> N/A
		<input type="checkbox"/> Fluidics <input type="checkbox"/> Verification <input type="checkbox"/> Calibration <input type="checkbox"/> Perform clog removal <input type="checkbox"/> Clean probe <input type="checkbox"/> N/A <input type="checkbox"/> Other:	<input type="checkbox"/> N/A

Comments:

☐ N/A

Review By/Date:

FLEXMAP 3D Performance Maintenance Form

Form ID: HSL_EQ_028.02

Document ID: HSL_EQ_028

Version 1.0

Page 1 of 1

Equipment ID:

Date	Analyst	Monthly Maintenance	Semi-Annual Maintenance	Annual Maintenance
		<input type="checkbox"/> N/A <input type="checkbox"/> Clean exterior surfaces	<input type="checkbox"/> N/A <input type="checkbox"/> Replace Teflon Seals <input type="checkbox"/> Replace HEPA Filter <input type="checkbox"/> Clean Ventilation Filters <input type="checkbox"/> Apply "PM" Sticker	<input type="checkbox"/> N/A <input type="checkbox"/> Replace Sheath Filter <input type="checkbox"/> Apply "PM" Sticker
		<input type="checkbox"/> N/A <input type="checkbox"/> Clean exterior surfaces	<input type="checkbox"/> N/A <input type="checkbox"/> Replace Teflon Seals <input type="checkbox"/> Replace HEPA Filter <input type="checkbox"/> Clean Ventilation Filters <input type="checkbox"/> Apply "PM" Sticker	<input type="checkbox"/> N/A <input type="checkbox"/> Replace Sheath Filter <input type="checkbox"/> Apply "PM" Sticker
		<input type="checkbox"/> N/A <input type="checkbox"/> Clean exterior surfaces	<input type="checkbox"/> N/A <input type="checkbox"/> Replace Teflon Seals <input type="checkbox"/> Replace HEPA Filter <input type="checkbox"/> Clean Ventilation Filters <input type="checkbox"/> Apply "PM" Sticker	<input type="checkbox"/> N/A <input type="checkbox"/> Replace Sheath Filter <input type="checkbox"/> Apply "PM" Sticker
		<input type="checkbox"/> N/A <input type="checkbox"/> Clean exterior surfaces	<input type="checkbox"/> N/A <input type="checkbox"/> Replace Teflon Seals <input type="checkbox"/> Replace HEPA Filter <input type="checkbox"/> Clean Ventilation Filters <input type="checkbox"/> Apply "PM" Sticker	<input type="checkbox"/> N/A <input type="checkbox"/> Replace Sheath Filter <input type="checkbox"/> Apply "PM" Sticker
		<input type="checkbox"/> N/A <input type="checkbox"/> Clean exterior surfaces	<input type="checkbox"/> N/A <input type="checkbox"/> Replace Teflon Seals <input type="checkbox"/> Replace HEPA Filter <input type="checkbox"/> Clean Ventilation Filters <input type="checkbox"/> Apply "PM" Sticker	<input type="checkbox"/> N/A <input type="checkbox"/> Replace Sheath Filter <input type="checkbox"/> Apply "PM" Sticker
		<input type="checkbox"/> N/A <input type="checkbox"/> Clean exterior surfaces	<input type="checkbox"/> N/A <input type="checkbox"/> Replace Teflon Seals <input type="checkbox"/> Replace HEPA Filter <input type="checkbox"/> Clean Ventilation Filters <input type="checkbox"/> Apply "PM" Sticker	<input type="checkbox"/> N/A <input type="checkbox"/> Replace Sheath Filter <input type="checkbox"/> Apply "PM" Sticker

Comments:

☐ N/A

Reviewed By/ Date: